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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/000,890 09/09/99 MOYER

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021835 HM12/0802
ELAN PHARMACEUTICALS, INC.
INTELLECTUAL PROPERTY DEPARTMENT
800 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO CA 94080

EXAMINER

DEVI, S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

08/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/393,590

Applicant(s)

Moyer et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/23/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above, claim(s) 29-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/23/01 (paper no. 11) in response to the Office Action mailed 10/24/00 (paper no. 8).

Status of Claims

- 2) Claims 1-58 are pending in the instant application.
Claims 2, 8 and 21 have been amended via the amendment filed 04/23/01.
Claims 1-28 are under examination.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' Information Disclosure Statement filed 04/23/01 (paper no. 10). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 12).

Objection(s) Maintained

- 4) The objection to the specification made in paragraph 6 of the Office Action mailed 10/24/00 is maintained for the reason set forth therein.

Objection(s) Withdrawn

- 5) The objection to claims 8 and 21 made in paragraph 10 of the Office Action mailed 10/24/00 is withdrawn in light of Applicants' amendments to the claims.

Rejection(s) Withdrawn

- 6) The rejection of claim 8 made in paragraph 8(a) of the Office Action mailed 10/24/00 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.
- 7) The rejection of claim 21 made in paragraph 8(b) of the Office Action mailed 10/24/00 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.
- 8) The rejection of claims 10-12 and 23-25 made in paragraph 8(c) of the Office Action mailed 10/24/00 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claim(s).

Rejection(s) Maintained

9) The rejection of claims 1-8, 12-22 and 25-28 made in paragraph 9 of the Office Action mailed 10/24/00 under 35 U.S.C § 112, first paragraph, with regard to the scope, is maintained for reasons set forth therein and here below. Claims 9-11, 23 and 24, which depend directly or indirectly, from claim 1 are now included in this rejection.

Applicants contend that the rejection is improper for failing to take into account all the Wands' factors in reaching a conclusion that undue experimentation would be required to practice the invention in respect to types of botulinum toxin other than type B. Applicants state that the Prevot reference is not useful in making an assessment of the state of the art as it is understood today. Applicants acknowledge that throughout the monograph, Prevot reports on the inconsistent behavior of the toxins under the same conditions of batches of the toxin, but opine that such inconsistency demonstrates that the purification of the toxin was not consistent or adequate. Applicants in essence assert that the unpredictability postulated by the Office based on the Prevot reference is largely due to the poor purification of the enzymes that could be accomplished using the technologies available in the late 40's and early 50's. Applicants contend that the instant specification in section III teaches methods of purification of both type A and B toxins to remove unwanted impurities that would adversely affect the long term stability of a toxin formulation and that one skilled in the art would understand how to adapt the disclosed methods to provide purified amounts of types C-G from the specification. Applicants cite *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976) and state their belief that they are entitled to the full scope of the claims.

Applicants' arguments have been carefully considered, but are not persuasive. Applicants are incorrect in stating that the rejection was based on the analysis of a single Wands' factor. See below. The teachings of the Prevot reference is relevant, because Applicants' botulinum toxin, as currently recited in the instant claims, is not a 'purified' toxin. Prevot teaches the unpredictability factor by stating that toxin E sometimes behaves like groups A and B botulinum toxins and sometimes like groups C and D toxins with regard to the preservation at +4 degree centigrade. The art also reflects batch-to-batch inconsistency in the stability of different botulinum toxins when stored at +4 degree centigrade at a pH between 5-6. The instant specification lacks

Serial Number 09/393,590

Art Unit: 1645

disclosure, adequate guidance/direction and working examples enabling a stable botulinum toxin formulation, as claimed, for any toxin other than type B toxin. Due to this art-recognized dissimilarity between the preservation properties of different botulinum toxins, the unpredictable stability, the lack of evidence in the instant disclosure that is commensurate in scope, the lack of sufficient and/or specific guidance, the breadth of claims and the quantity of experimentation necessary, undue experimentation would have been required by one of ordinary skill in the art to reproducibly practice the full scope of the invention as claimed. The instant claims are viewed as not meeting the provisions of 35 U.S.C. § 112, first paragraph.

Remarks

10) Claims 1-28 stand rejected.

11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

12) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



S. Devi, Ph.D.

Primary Examiner

July 2001